

Butler, Jennie C

From: Account DRUGINFO. [DRUGINFO@cder.fda.gov]
Sent: Monday, June 07, 1999 11:38 AM
To: Richman, Fred
Subject: FWD: FDA Comments

Sensitivity: Confidential



FDA Comments

FYI

E-Mail: schwadb@yahoo.com

Comments: DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE, MD 20857-0003

RE: DOCKET NO. 98N-1265

To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU must be amended!!!

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!

Signed: David B Schwartz, Marilyn R Schwartz

State of Residence: LA

98N-1265

C3294